

Attachment V
Special 510(K) Summary
LS-40 CO2 Laser System

K093793

FEB 18 2010

This 510(K) Summary of safety and effectiveness for the LS-40 CO2 Laser System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Sandstone Medical Technologies, LLC
Address:	105 Citation Street Homewood, AL 35209
Contact Person:	Mark Rohrer
Telephone and Email:	205-290-8251 – phone ssmed@bellsouth.net
Preparation Date:	December 2, 2009
Device Trade Name:	LS-40 CO2 Laser System
Common Name:	CO2 Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Predicate Device:	LS-25 Family of CO2 Laser Systems K040563
Description of the Enlyten System	The LS-40 CO2 Laser System is a microprocessor-controlled CO2 laser system using a sealed CO2 laser tube providing 40 watts maximum power. The system incorporates a CO2 laser tube within the main cabinet, an articulated arm beam delivery system and attachable laser accessories. The unit is activated for laser emission by a footswitch.
Intended use of the Enlyten System:	The LS-40 CO2 Laser System is intended to be used for Coagulation, Vaporization, Ablation or cutting of soft tissue in dermatology and plastic surgery, general surgery, podiatry and otorhinolaryngology.
Performance Data:	None
Results of Clinical Study:	None
Conclusion:	The LS-40 CO2 Laser System is substantially equivalent to the previously cleared LS Family of CO2 Lasers that is in commercial distribution for use in Dermatology and Plastic Surgery.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Sandstone Medical Technologies, LLC
% Mr. Mark Rohrer
105 Citation Court
Homewood, Alabama 35209

FEB 18 2010

Re: K093793

Trade/Device Name: LS-40 CO2 Surgical Laser System

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: January 18, 2010

Received: January 19, 2010

Dear Mr. Rohrer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

FOR

Mark N. Melkerson

Director

Division of Surgical, Orthopedic
and Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

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Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: LS-40 CO2 Surgical Laser System

Indications for Use:

Coagulation, vaporization, ablation or cutting of soft tissue in dermatology and plastic surgery, general surgery, podiatry and otorhinolaryngology.


Prescription Use xx
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

FOR M. MELKERSON

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